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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/572,563
Filing Date: September 14, 2004
Applicant: Jiunn-Liang KO et al.
Group Art Unit: Unknown
Examiner: Unknown
Title: Fungal Immunomodulatory Protein (FIP) Prepared by
Microorganisms and Uses Thereof
Attorney Docket: 8964-000031/US

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Randolph Building
401 Dulany Street
Alexandria, VA 22314
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February 1, 2007

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, Applicant hereby submits an Information Disclosure Statement for consideration by the Examiner.

I. **LIST OF PATENTS, PUBLICATIONS, AND OTHER INFORMATION**

The patents, publications and other information submitted for consideration by the Office (except unpublished U.S. patent applications) are listed on Form PTO-1449 attached hereto.

II. **COPIES**

A. ☐ Submitted herewith is a legible copy of (i) each foreign patent; (ii) each publication or that portion which caused it to be listed, other than U.S. patents and U.S. patent application publications unless required by the Office; (iii) for each cited pending unpublished U.S. application listed below in Section IV, the application specification including the claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion; and (iv) all other information or that portion which caused it to be listed.

B. ☐ Any patents, publications or other information which are listed on Form PTO-1449 or on the copies of Form PTO-892, but which are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

U.S. Serial Number

U.S. Filing Date

C. ☒ Because the present application was/is being filed after June 30, 2003, no copies of the U.S. patents or U.S. patent application publications which are listed on the attached Form PTO-1449 are enclosed pursuant to the waiver of 37 C.F.R. § 1.98(a)(2)(i). Any foreign patent documents or non-patent literature listed on the attached Form PTO-1449 are enclosed herewith.

D. ☐ This is a PCT application in the entry of the National Phase in the United States. A copy of the International Search Report is attached for the Examiner's information. The documents listed on the International Search Report are listed on the attached Form PTO-1449 for consideration by the Examiner and for listing on any patent resulting from this application. Since the International Search Report was from the US, EPO, or JPO search authorities, copies of these references should have been supplied to the USPTO under the trilateral agreement and are believed to be in the file of the above-identified application. (MPEP 1893.03(g))

III. CONCISE EXPLANATION OF THE RELEVANCE (check at least one box)

A. ☒ Except as may be indicated below in (B), all of the patents, publications or other information are in the English language (concise explanation not required).

B. ☒ A concise explanation of the relevance of each patent, publication or other information listed that is not in the English language is as follows (see 37 C.F.R. § 1.98(a)(3)):

1. ☒ See the attached foreign patent office communication from a counterpart foreign application: International Search Report of the parent PCT application (PCT/CN2004/001044) dated December 9, 2004.
2. ☒ English abstracts are provided for JP 02-032026, Boping et al.,
Prokaryotic Expressing of LZ-8 Gene in E-Coli and Saihong et al.,
A Survey of Pharmacodynamic Study of Lucid Ganoderma.
3. ☐ Other:

C. ☐ The following additional information is provided for the Examiner's consideration.

IV. CROSS REFERENCE TO RELATED APPLICATION(S)

A. ☐ The Examiner is advised that the following co-pending application(s) contain(s) subject matter that may be related to the present application. By bringing this(these) application(s) to the Examiner's attention, Applicant(s) does(do) not waive the confidentiality provisions of 35 U.S.C. § 122.

Serial No.

Filing Date

Art Unit

V. THIS IDS IS BEING FILED UNDER

A. ☒ 37 C.F.R. § 1.97(b): (check only one box)

1. ☐ within three months of the filing date of a national application other than a continued prosecution application under 37 C.F.R. § 1.53(d) (37 C.F.R. § 1.97(b)(1)). No fee or certification is required.
2. ☐ within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or certification is required.
3. ☒ before the mailing of a first Office Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or certification is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the certification under 37 C.F.R. § 1.97(e) below; or, if no certification has been made, charge our deposit account a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).
4. ☐ before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No fee or certification is required.

B. ☐ 37 C.F.R. § 1.97(c): (check only one box)

- ☐ before the mailing date of either any Final Office Action under 37 C.F.R. § 1.113, a Notice of Allowance under 37 C.F.R. § 1.311, or an action that otherwise closes prosecution.
1. ☐ No certification; therefore, a fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).
 2. ☐ See the certification below. No fee is required.

C. ☐ 37 C.F.R. § 1.97(d):

- ☐ after the mailing date of either a Final Office Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311, yet on or before payment of the issue fee.
1. ☐ See the certification below. A fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).

VI. CERTIFICATION UNDER 37 C.F.R. § 1.97(e): (check only one box)

The undersigned hereby certifies that:

- A. ☐ each item of information contained in this IDS was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS (See 37 C.F.R. § 1.97(e)(1)). See further statement under 37 C.F.R. § 1.704(d) below in section VII, if applicable; or
- B. ☐ no item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this IDS (See 37 C.F.R. § 1.97(e)(2)).
- C. ☐ Some of the items of information were first cited in a communication from a foreign patent office. As to this information, the undersigned hereby certifies that each item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby certifies that no item of this remaining information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this IDS.

VII. STATEMENT UNDER 37 C.F.R. § 1.704(d)

The undersigned hereby states that:

☐ each item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this IDS.

VIII. PAYMENT OF FEES (check only one box)

- A. ☒ No fee is believed to be due in light of the above-noted status or above-provided certification.
- B. ☐ A check in the amount of \$180.00 is enclosed for the above-identified fee.
- C. ☐ Please charge Deposit Account No. 08-0750 in the amount of \$180.00 for the above-indicated fee. A duplicate copy of this paper is attached.

The above references are being cited only in the interest of candor and without any admission that they constitute statutory prior art, contain matter which anticipates the invention, or which would render the same obvious, either singly or in combination, to a person of ordinary skill in the art. Furthermore, this Information Disclosure Statement shall not be construed as a representation that a search has been made.

If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition if necessary) and charge the appropriate fee to Deposit Account No. 08-0750.

Please charge any additional fees or credit any overpayment pursuant to 37 C.F.R. §§ 1.16 or 1.17 to Deposit Account No. 08-0750.

Respectfully submitted,

HARNESS, DICKEY, & PIERCE, P.L.C.

By 
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JAC/GPB:ame

Enclosures: ☒ Form PTO-1449(s) (1 sheet(s))
☒ Documents
☒ International Search Report
☐ Fee
☐ Other:



FORM HDP-1449 (Based on Form PTO-1)

PATENT AND TRADEMARK OFFICE
INFORMATION DISCLOSURE CITATION
 (Use several sheets if necessary)

Sheet 1 of 2

ATTORNEY DOCKET NO.	SERIAL NO.
8964-000031/US	10/572,563
APPLICANT	
Jiunn-Liang KO et al.	
FILING DATE	GROUP
September 14, 2004	

U.S. PATENT DOCUMENTS

Ref. Desig.	Examiner's Initials	Document Number	Date	Name	Class/ Subclass	(If appropriate) Filing Date
1.		5,334,704	08/02/1994	Tsunoo et al.	530/371	

FOREIGN PATENT DOCUMENTS

Ref. Desig.	Examiner's Initials	Document Number	Date	Country	Class/ Subclass	Translation Yes No	
2.		02-032026	02/01/1990	Japan		X - abstract	

OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)

Ref. Desig.	Examiner's Initials	
3.		Allione A, et al., <i>β-Galactoside-Binding Protein (βGBP) Alters the Cell Cycle, Up-Regulates Expression of the α- and β-Chains of the IFN-γ Receptor, and Triggers IFN-γ-Mediated Apoptosis of Activated Human T Lymphocytes</i> , J. IMMUNOL. 161:2114-2119 (1998)
4.		Black PH, <i>The Inflammatory Response is an Integral Part of the Stress Response: Implications for Atherosclerosis, Insulin Resistance, Type II Diabetes and Metabolic Syndrome X</i> , BRAIN BEHAV IMMUN. 17:350-364 (2003)
5.		Boping YE, et al., <i>Prokaryotic Expressing of LZ-8 Gene in E-Coli</i> , PHARM . BIOTECHNOL. 9:21-23 (2002)
6.		Chen HY, et al., <i>In Vivo Anti-Candidal Activity Induced by a Traditional Chinese Herbal Medicine, Ganoderma Lucidum</i> , JPN. J. MED. MYCOL. 33:505-512 (1992)
7.		Couraud PO, et al., <i>Molecular Cloning, Characterization, and Expression of a Human 14-kDa Lectin</i> , J. BIOL.CHEM., 264:1310-1316 (1989)
8.		Engelsma MY, et al., <i>Multiple Acute Temperature Stress Affects Leucocyte Populations and Antibody Responses in Common Carp, Cyprinus Carpio L.</i> , FISH SHELLFISH IMMUNOL. 15:397-410 (2003)
9.		Gabius HJ, et al., <i>The Immunomodulatory β-Galactoside-Specific Lectin from Mistletoe: Partial Sequence Analysis, Cell and Tissue Binding, and Impact on Intracellular Biosignalling of Monocytic Leukemia Cells</i> , ANTICANCER RES. 12:669-676 (1992)
10.		Horner WE, et al., <i>Basidiomycete Allergens: Comparison of Three Ganoderma Species</i> , ALLERGY 48:110-116 (1993)

Examiner:

Date Considered:

EXAMINER: Please initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



FORM HDP-1449 (Based on Form PTO-1449)

PATENT AND TRADEMARK OFFICE
INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)

Sheet 2 of 2

ATTORNEY DOCKET NO.

SERIAL NO.

8964-000031/US

10/572,563

APPLICANT

Jiunn-Liang KO et al.

FILING DATE

GROUP

September 14, 2004

OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)

Ref. Desig.	Examiner's Initials	
11.		Jayaraman K, et al., <i>Polymerase Chain Reaction-Mediated Gene Synthesis: Synthesis of a Gene Coding for Isozyme C of Horseradish Peroxidase</i> , PROC. NATL. ACAD. SCI. USA. 88:4084-4088 (1991)
12.		Kawagishi H, et al., <i>5'-Deoxy-5'-Methylsulphinyladenine, A Platelet Aggregation Inhibitor from Ganoderma Lucidum</i> , PHYTOCHEMISTRY 32:239-240 (1993)
13.		Kino K, et al., <i>Isolation and Characterization of a New Immunomodulatory Protein, Ling Zhi-8 (LZ-8), from Ganoderma Lucidum</i> , J. BIOL. CHEM. 264:472-478 (1989)
14.		Ko JL, et al., <i>A New Fungal Immunomodulatory Protein, FIP-fve Isolated From the Edible Mushroom, Flammulina Velutipes and Its Complete Amino Acid Sequence</i> , EUR. J. BIOCHEM. 228:244-249 (1995)
15.		Laemmli, UK, et al., <i>Cleavage of Structural Proteins During the Assembly of the Head of Bacteriophage T4</i> , NATURE 227:680-685 (1970)
16.		Lin JM, et al., <i>Evaluation of the Anti-Inflammatory and Liver-Protective Effects of Anoectochilus Formosanus, Ganoderma Lucidum and Gynostemma Pentaphyllum in Rats</i> , AM. J. CHIN. MED. 21:59-69 (1993)
17.		<i>Molecular Cloning: A LABORATORY MANUAL</i> , 2 ND ED., 1.82-1.84 (1989)
18.		<i>Molecular Cloning: A LABORATORY MANUAL</i> , 2 ND ED., 18.60-18.75 (1989)
19.		Murasugi A, et al., <i>Molecular Cloning of a cDNA and a Gene Encoding an Immunomodulatory Protein, Ling Zhi-8, from a Fungus, Ganoderma Lucidum</i> , J. BIOL. CHEM. 266:2486-2493 (1991)
20.		Romanos MA, et al., <i>Foreign Gene Expression in Yeast: a Review</i> , YEAST 8:423-488 (1992)
21.		Sorensen MA, et al., <i>Absolute in Vivo Translation Rates of Individual Codons in Escherichia Coli the Two Glutamic Acid Codons GAA and GAG are Translated with a Threefold Difference in Rate</i> , J. MOL. BIOL. 222:265-280 (1991)
22.		Saihong, Q, et al., <i>A Survey of Pharmacodynamic Study on Lucid Ganoderma</i> , HUNAN GUIDING JOURNAL OF TC MP 5:19-21 (1999)
23.		Wasser SP, et al., <i>Therapeutic Effects of Substances Occurring in Higher Basidiomycetes Mushrooms: A Modern Perspective</i> , CRIT. REV. IMMUNO. 19:65-96 (1999)
24.		Weisbart RH, et al., <i>Nuclear Delivery of p53 C-Terminal Peptides Into Cancer Cells Using scFv Fragments of a Monoclonal Antibody That Penetrates Living Cells</i> , CANCER LETT. 195:211-219 (2003)
25.		International Search Report for International Patent Application No. PCT/CN2004/001044

Examiner:

Date Considered:

EXAMINER: Please initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.